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EPIDEMIOLOGIC AND ECONOMIC IMPACT OF ROUTINE VACCINATION OF INFANTS AGAINST ROTAVIRUS GASTROENTERITIS IN GERMANY: A PRELIMINARY ANALYSIS

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OBJECTIVES: Rotavirus gastroenteritis (RVGE) is among the most common reasons for physician consultations during the first year's of life. RVGE can be prevented by vaccination. The objective was to analyse the clinical and economic impact of universal rotavirus vaccination of infants in Germany. **METHODS:** A Markov model was developed and calibrated to reflect observed epidemiological data. In the model, a cohort of 670,000 newborns was followed over five years. Routine vaccination with the oral vaccine Rotarix™ was compared with no vaccination. Efficacy derived from a European phase-III trial (eTrack102247/NCT140686) demonstrated 87% efficacy against RVGE of any severity, 96% against severe RVGE and 100% against hospitalisation due to RVGE. Total costs to society were 432 € per outpatient, 2,085 € per community-acquired hospitalization, and 478 € for nosocomial RV cases. Utility values were 0.546 for mild, 0.339 for severe, 0.312 for hospitalized, and 0.501 for nosocomial cases. Cost/effects were discounted by 4.0%/1.5%. Sensitivity analyses were conducted on costs $\pm 15\%$, utilities $\pm 15\%$, efficacy (95%CI), discounting and vaccine price (within pharmacy mark-up differences anticipated with a larger pack-size). **RESULTS:** In the cohort, 182,820 community-acquired cases (140,785 presenting to physicians and of those 33,081 were hospitalized) and 19,848 nosocomial cases occurred resulting in costs of 128.2 mio. €. The overall number of cases could be reduced by 82.0%. Approximately 4 children had to be vaccinated to prevent one RV case and 21 children had to be vaccinated to prevent one community-acquired, hospitalized case. Cost-effectiveness was 3,770 € per QALY. Cost/QALY was below 15,000 € for all sensitivity analyses, the cost/QALY being most sensitive to variations in cost assumptions. At higher costs, lower vaccine price and without discounting, vaccination was cost-saving. **CONCLUSION:** Rotavirus causes a considerable burden of disease and associated costs. Universal vaccination of infants is a cost-effective approach to reducing this socio-economic burden.

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BURDEN OF PAEDIATRIC ROTAVIRUS GASTROENTERITIS AND POTENTIAL BENEFITS OF A UNIVERSAL VACCINATION PROGRAMME IN GERMANY

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OBJECTIVES: Rotavirus is the most common cause of gastroenteritis in young children worldwide, resulting in a high burden of disease. The objective of this study was to evaluate the effects of vaccinating infants with a pentavalent rotavirus vaccine, RotaTeg®, in Germany. **METHODS:** Using a decision analytic model a birth cohort of 705,622 newborns was followed from birth up to 5 years of age. Total societal cost associated with rotavirus gastroenteritis in this cohort was calculated. Potential costs and benefits of a universal rotavirus vaccination programme were assessed. Input parameters were derived from a German prospective epidemiological study ("REVEAL study"),

national statistics and published literature. Efficacy of RotaTeg® (prevention of 86% office visits, of 96% hospitalisations) was based on a large clinical trial ("REST Efficacy Study", Phase III). Main outcome measures were cases avoided, total societal direct and indirect disease costs and vaccination expenditures of Sickness Funds (administration fees & vaccine costs). Cost per avoided case was used as a measure of cost-effectiveness. In addition, the number needed to vaccinate (NNV) was calculated. **RESULTS:** A rotavirus vaccination programme with a coverage rate of 90% would prevent in total about 325,565 cases of rotavirus infections in Germany (~75%) and the huge burden of human suffering behind these cases. Total societal costs associated with paediatric rotavirus gastro-enteritis are estimated at €119.2 million. The vaccination programme with cost of €117.2 million could reduce the societal disease costs by €91.8 million (~77%). This leads to costs per hospitalised case avoided of €1405.70 and a NNV of 35 infants. To avoid 1 general practitioner/paediatrician case the NNV is 6 with costs per case prevented of €191.90. **CONCLUSION:** Implementing a rotavirus vaccination programme in Germany with RotaTeg® will significantly and efficiently decrease the morbidity and associated burden due to rotavirus infections in young children. ~2007->.

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COST EFFECTIVENESS OF THE MF59-ADJUVANTED INFLUENZA VACCINE IN FRANCE: THE "AT-RISK" ADULT POPULATION

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OBJECTIVES: To evaluate the cost-effectiveness of the MF59 adjuvanted influenza vaccine versus non-adjuvanted vaccine in the "at risk" adult population (age 18–64) in France. A central feature of the analysis was the occurrence of antigenic drift and its effect on vaccination efficacy against influenza. Antigenic drift is a mutation in the influenza virus, so that an immune system response that combats influenza one year may not provide complete protection the following year. **METHODS:** A decision-analytic model was developed using evidence from clinical studies to compare relative effectiveness of MF59 adjuvanted influenza vaccine and non-adjuvanted vaccine in years when antigenic drift occurs. Data on the impact on hospitalisations, GP visits and mortality was taken from a case-control study, with other resource use parameters and costs from the literature. The analysis was performed from the payer perspective (direct medical costs) for "at risk" adults in France. "At risk" is defined as persons with comorbidities such as diabetes and respiratory problems who have elevated risk of developing complications. **RESULTS:** MF59 adjuvanted influenza vaccine maintains effectiveness post antigenic drift more than non-adjuvanted vaccines. It was estimated that in an average year 14% of viral strains drift. Using this estimate, for an attack rate of influenza-like illness of 6% and a 3% discount rate, the incremental cost per life year gained (ICLYG) was €19,358. In a pessimistic scenario where 100% of viral strains drift, the ICLYG was €204. ICLYG was most sensitive to hospitalisation rate, extent of antigenic drift and vaccine price. **CONCLUSION:** The incremental CLYG is well within acceptable European thresholds. Compared to non-adjuvanted vaccines, MF59 adjuvanted vaccine can be considered cost-effective for the "at risk" adult population aged <65 years in France and close to cost-neutral in years when antigenic drift occurs, protecting better individuals at higher risk of complications and hospitalisation.